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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PHILIP S. JOHNSON				FERNANDEZ, KATHERINE L
JOHNSON & JOHNSON		ART UNIT		PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/567,235	COLQUHOUN, CALLUM
	Examiner	Art Unit
	KATHERINE L. FERNANDEZ	3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 1/10/08.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-13 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-13 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 2/3/2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

Claim Objections

1. Claim 7 is objected to because of the following informalities:

Claim 7 recites the limitation "the outer diameter" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
3. Claims 1-4 and 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martinelli et al. (WO 01/30257) in view of White et al. (US Patent No. 6,656,184).

Martinelli et al. disclose a bone marker for use in image guided surgery, comprising: a support having an anchor mechanism for anchoring the support in a bone (pg. 5, lines 4-17), at least one reference member detectable by an image guided system, the at least one reference member being attached to the support (pg. 5, lines 4-17; pg. 7, line 18-pg. 8, line 13). The support further comprises at least one limb which is rigid (pg. 5, lines 4-18; pg. 7, line 18-pg. 8, line 13). The anchor mechanism comprises at least one fixation member, such as a threaded screw (14), for anchoring the bone marker in the bone, and a coupling member for coupling the support to the fixation member, wherein the coupling member is adjustable to allow rotation of the support about the fixation member (pg. 5, lines 4-17; pg. 7, line 18-pg. 8, line 6). The

diameter of the threaded screw is not more than about 2 mm (pg. 5, lines 4-17). The reference members transmit signals (pg. 5, line 23-pg. line 17).

However, they do not specifically disclose that the support comprises at least one limb that is resiliently deformable, wherein the resiliently deformable limb comprises a tightly wound helical spring, and wherein the spring has flat abutting surfaces and that the ratio of an outer diameter of the resiliently deformable limb to its inner diameter is at most 3:1. White et al. disclose a bone screw having an intermediate helical spring portion, wherein a resorbable material is disposed within the spaces of the helical spring portion when the bone screw is in a stressed state, so as to provide various rates of compliant fixation (column 1, lines 6-11). They disclose that the rigidity of typical bone screws cause the surrounding bone to fail because the bone has lower strength and stiffness than the bone screw, which can lead to failure of the fixation and eventual non-union or misalignment of the bone member of a fracture site (column 1, lines 24-41). Their bone screw includes three primary portions: a distal portion having a threaded surface formed thereon by any number of conventional milling methods, a proximal head portion having a recess formed therein for receiving a driving device, and an intermediate portion having a compressive member (i.e. helical spring with flat abutting surfaces (see element (20), Figures 1-2)), such as but not limited to a single or double helix (column 4, lines 14-41). The compressive member is allowed to return to its relaxed state after being stressed (column 6, lines 22-43). As can be seen in Figures 1-2, the ratio of the outer diameter of the compressive member (20) is at most 3:1. At the time of the invention, it would have been obvious to one of ordinary skill in the art to

modify the invention of Martinelli et al. to modify the support to comprise a limb that is resiliently deformable (i.e. tightly wound helical spring), wherein the spring has flat abutting surfaces and wherein the ratio of an outer diameter of the resiliently deformable limb to its inner diameter is at most 3:1, as taught by White et al., in order to conserve moderate tension in the bone marker over time and to provide various rates of compliant fixation (column 1, lines 5-11, 34-41; column 2, lines 15-28).

4. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martinelli et al. in view of White et al. as applied to claim 1 above, and further in view of Nassar et al. (US Patent No. 5,389,107).

As discussed above, the above combined reference meet the limitations of claim 1. However, they do not specifically disclose that the deformable limb is made from a damped elastomer. Nassar et al. disclose a shock absorbent prosthetic hip joint, which significantly dampens the force of impact caused by walking, running or similar activities (column 1, lines 8-10). They disclose that their shock absorbent hip joint can comprise of a volumetric spring that can comprise of a plurality of resilient spherical elements composed of a suitable elastomer (column 4, lines 44-61). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Martinelli et al. in view of White et al. to have the resiliently deformable limb be made from a damped elastomer, as Nassar et al. teaches the use of an elastomer as a resiliently deformable material.

5. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martinelli et al. in view of White et al. as applied to claim 1 above, and further in view of Lieberman (US Patent No. 6,527,774).

As discussed above, the above combined references meet the limitations of claim 1. However, they do not specifically disclose that the deformable limb is made from a shape memory alloy. Lieberman discloses an apparatus for attaching fractured sections of bone in a patient's body, and which prevents relative rotation of the fractured sections of bone without damaging the sections (column 1, lines 18-24). They disclose that their apparatus comprises a bone screw having a platform for drivingly rotating the bone screw and at least two helical spikes for embedding into at least one of the first and second sections of the bone upon rotation of the platform (column 2, lines 23-43). They disclose that the bone screw and the helical spikes can be made from a shape memory alloy, which has the ability to return to a predetermined shape (column 10, lines 34-60). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the deformable limb of Martinelli et al. in view of White et al. be made from a shape memory alloy, as taught by Lieberman et al., shape memory materials have the ability to return to a predetermined shape.

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martinelli et al. in view of White et al. as applied to claim 1 above, and further in view of Henderson et al. (US Patent No. 6,591,699).

As discussed above, the above combined references meet the limitations of claim 1. Martinelli et al. further disclose that their invention is not limited to any specific

localization guidance system or algorithm (pg. 5, lines 28-29). However, they do not specifically disclose that the reference members reflect signals. Henderson et al. disclose a reference frame and instrument guide frame for use in an image guided surgery navigation system (column 1, lines 12-19). They disclose that their invention includes an instrument guide unit that is used to guide a surgical instrument during a surgical operation, wherein the surgical instrument includes a tracking marker, such as an LED, that is detected or monitored by a sensor array (column 3, lines 29-54). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Martinelli et al. in view of White et al. to have the reference member reflect light, as Martinelli et al. in view of White et al. require a reference member detectable by an image guided system, and Henderson et al. teach the use of a reference member that reflects signals (i.e. LED) as a suitable reference member detectable by an image guided system (column 3, lines 29-54).

Response to Arguments

7. Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768